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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,115	06/23/2005	Ola Karlsson	1103326-0781	8848

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EXAMINER	
WU, IVES J	
ART UNIT	**PAPER NUMBER**
1797	

MAIL DATE	DELIVERY MODE
09/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,115	KARLSSON ET AL.	
	Examiner	Art Unit	
	IVES WU	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-16,27-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *3-16 and 27-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/15/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

(1). Applicants' Amendments filed on 07/18/2008 and Remarks filed on 04/30/2008 have been received.

Claims 3 - 9 are amended. Claims 1-2 and 17-26 are cancelled before.

The 112 rejections of claims 7-8 in prior Office Action dated 10/31/2007 is withdrawn in view of the current Amendments and Remarks.

The rejections for claims 3-16 and 27-32 in prior Office Action dated 10/31/2007 are revised in according to the current Amendments and presented hereafter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(2). **Claims 3-16** and **27-32** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "substantially un-crosslinked" in claims 3-8 renders the claims indefinite because the requisite degree of un-crosslink is unclear. The phrase "substantially un-crosslinked" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 9-16 and **27-32** are rejected because they are depend claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(3). **Claims 3-6, 31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinecke et al (US04056497) in view of Greenwald et al (US03944513).

Reinecke et al (US004056497) disclose a acrylic ester copolymers obtained by copolymerizing acrylic esters with α-haloalkanecarboxylic acid vinyl esters and α,β-ethylenically

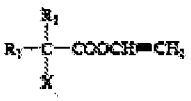
unsaturated carboxylic acids and optionally other unsaturated monomers in **aqueous dispersion**. The copolymers **can be cross-linked with alkalies after the polymerization** (Abstract, line 1-5).

The present patentee's invention provides a process for the preparation of aqueous copolymer dispersions capable of being cross-linked in the presence of alkalies by polymerization of a mixture of:

a. 60 to 95 wt%, calculated on the monomer mixture, of at least one acrylic acid ester and/or methacrylic acid ester of a saturated aliphatic alcohol having from 1 to 20 carbon atoms,

b. 0 to 40 wt%, calculated on the monomer mixture, of monomers the homopolymers of which have 2nd order Tg of from –40°C to +150 °C and

c. 0.1 to 10 wt%, calculated on the monomer mixture, of an α-haloalkanecarboxylic acid vinyl esters of the formula (I)

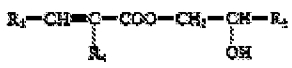


(I)

wherein R_1 and R_2 each represents hydrogen or an alkyl radical having from 1 to 5 carbon atoms and X is fluorine, chlorine, bromine or iodine, in aqueous dispersion in the presence of emulsifiers and/or protective colloids and of free radical initiators, which process comprises using as further reactive monomers

d. 0.1 to 10 wt%, calculated on the monomer mixture of, α,β-ethylenically unsaturated carboxylic acids having from 3 to 8 carbon atoms or their partial ester with saturated aliphatic alcohols having from 1 to 20 carbon atoms and,

e. 0 to 10 wt%, calculated on the monomer mixture, of monomers containing hydroxyl groups and having the formula (II)



(II)

wherein R_3 is hydrogen, a methyl group or the group $-COOR_6$, R_4 and R_5 each is hydrogen or a methyl group and R_6 is hydrogen or an alkyl group having from 1 to 12 carbon atoms.

(Col. 1, line 57 – Col. 2, line 32)

The dispersions of patentee's invention are prepared by free radical polymerization of the monomers in **aqueous dispersion using emulsifiers**, protective colloids and, optionally regulators (Col. 3, line 12-15). The polymerization temperature is within the range of from 0 °C

to + 100 °C, preferably from 20° to 80°C (Col. 3, line 27-29). A foil of polyethylene terephthalate of a 2.5 cm X 20 cm dimension was provided with an adhesive layer 0.3 mm thick (application in wet state). After drying, the foil was joined under slight pressure to a carefully cleaned steel sheet for measurement of the resistance to peeling (kp/2.5 cm) (Col. 6, line 28-34).

As to the components of acrylic acid or an ester in the range 40 to 80 wt% , methacrylic acid or an ester in the range 20 to 60 wt% in **claims 3-4**, Reinecke et al disclose component (a) from 60 to 95 wt% including at least one acrylic acid ester and methacrylic acid ester of a saturated aliphatic alcohol having C_{1-20}. The range of 60 to 95wt% would include the acrylic acid ester such as ethyl acrylate in the range from 40 to 80 wt% and methacrylic acid ester such as methyl methacrylate in the range from 20 to 60 wt% as claimed.

As to the polymerizable surfactant in the range 0.01 to 9 wt% in **claims 3-4** and **31**, Reinecke et al disclose the component (e) having the formula (II) which is equivalent to formula (I) as claimed, when the setting of patentee's formula (II) are R_3 = H atom, R_4 = H atom or methyl group, R_5 = H, and setting of applicant's formula (I) are R_2 = H atom, m = 1. Since the disclosure of the monomer by Reinecke et al is identical to the formula (I) as claimed. It is reasonable to presume that the component (e) of Reinecke et al would fulfill the utility to be a polymerizable surfactant as presently claimed in light of their chemical similarity. The burden is shifted to applicants to establish that the polymerizable surfactant of the present claims is not the same as or obvious as that set forth by Reinecke et al.

As to an aqueous film coating dispersion for pharmaceutical formulations in **independent claim 3-4**, because the composition of aqueous polymer dispersion disclosed by Reinecke et al (US04056497) is substantially identical to the aqueous film coating dispersion of applicants, it will be useful in film coating for pharmaceutical formulations as well. The intended use is not considered as limitation and of no significance in the claim construction.

As to substantially free of residual emulsifying agent which is removed after the polymerization reaction in **independent claims 3-4**, Reinecke et al is silence about removal of emulsifier.

However, Greenwald et al (US03944513) **teach** purification of polymer dispersions with adsorbent carbon particles (Title).

The advantage of removing emulsifiers is for the reasons that aqueous dispersions of vinyl polymers often contain impurities, including volatile and nonvolatile materials, which may impart undesirable properties to the polymer such as haze, color and odor, and detract from desirable properties such as strength, toughness, flexibility, water resistance and electrical properties. Such impurities may include un-polymerized monomers, initiators such as potassium persulfate, chain transfer agent such as mercaptans, emulsifiers, impurities introduced with these materials, and the reaction products or degradation products thereof. The impurities may be in or on the polymer particles as well as in the aqueous phase (Col. 1, line 9-21).

Therefore, it would have been obvious at time of the invention to remove the emulsifier disclosed by Greenwald et al for the aqueous acrylate ester copolymer of Reinecke et al in order to obtain the above-cited advantage.

As to the aqueous film coating dispersion for pharmaceutical formulations, monomers, their wt percentage, formula (I) of the monomer and emulsifier being removed after the polymerization in **claims 5-6**, the disclosure of Reinecke et al (US004056497) is incorporated herein by reference, the most subject matters as currently claimed have been recited in applicants' claims 3 and 4, and have been discussed therein.

As to the molecular weight of emulsifier to be less than 15kD in **claims 5** and **6**, in view of substantially identical aqueous polymer dispersion disclosed by Reinecke et al, and by applicants, it is examiner's position to believe that the emulsifier of prior art would inherently possess the molecular weight as claimed. Since USOPTO does not have facilities to perform the measurement, the burden now is shifted to applicants to prove otherwise. *In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).*

(4). **Claims 9-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over combined teaching of Reinecke et al (US004056497), Greenwald et al (US03944513) and Barry et al (US005055306).

As to step of applying the aqueous dispersion to the surface of the dosage form and removing water from the aqueous dispersion to obtain film in a pharmaceutical coating film in **claim 9**, Barry et al (US005055306) disclose the coating being prepared by forming a solution and mixing it with a dispersion of a water insoluble but water swellable acrylic polymer. The

aqueous mixture is then used to coat the dried granules, and the coated granules are subsequently dried (Col. 8, line 37-43). Obviously, the water is removed and film is formed after the coating is dried.

However, it would have been obvious at time of the invention to use the acrylic ester copolymer of Reinecke et al et al for the coating film of pharmaceutical formulation of Barry et al because the acrylic ester polymer taught by Barry et al is a genus, the acrylic ester copolymer taught by Reinecke et al is species, one of ordinary skills in the art would expect all species work successfully for the genus, motivated by a reasonable expectation of success. *In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).*

As to the pharmaceutical formulation in **claim 10**, Barry et al (US005055306) **teach** a sustained-release formulation comprising a core comprising one or more pharmacologically active substances and preferably one or more excipients; and a coating covering substantially the whole surface of the core comprising 100 parts of a water insoluble but water swellable acrylic polymer and from 20 to 70 parts of a water soluble hydroxylated cellulose derivative (Abstract, line 9-17). The acrylic polymer component of the coating is preferably neutral and may comprise a homopolymer or a copolymer, for instance of acrylic acid esters or methacrylic acid esters. Preferably, the acrylic polymer is provided as an aqueous dispersion (Col. 6, line 60-64).

As to limitation of **claim 11**, Barry et al **teach** a granular sustained-release formulation of a pharmacologically active substance presented in the form of a tablet, tablet comprising sufficient granules to provide a predetermined dose or number of dose of pharmacologically active substance and effervescent or water-dispersible ingredients (Abstract, line 1-6). The coating is prepared by forming a solution of, for example, a water soluble hydroxylated cellulose derivative and mixing it with a dispersion of a water swellable acrylic polymer. The aqueous mixture is then used to coat the dried granules, and the coated granules are subsequently dried. (Col. 8, line 38-45). It will be appreciated that the term "granules" as used is intended to also cover other similar particles that might, in conventional sustained-release formulations, normally be referred to as beads or pellets, etc (Col. 8, line 64-68).

As to limitation of **claim 12**, Barry et al disclose the sustained-release formulation (Title).

As to limitation of **claims 13** and **14**, Barry et al disclose, for instance, the pharmacologically active substances that can be used in the sustained-release formulations

includes: drug acting on the gastrointestinal system (such as cimetidine), the cardiovascular system (such as anti-arrythmics e.g. verapamil; beta-adrenoceptor blockers e.g. propranolol, atenolol; anti-hypertensives e.g. methyldopa, levodopa and prazosin) (Col. 7, line 6-13).

(5). **Claims 15** and **16** is rejected under 35 U.S.C. 103(a) as being unpatentable over combined teaching of Reinecke et al (US004056497), Greenwald et al (US03944513), Barry et al (US005055306), further in view of Chen (US005939578A), evidenced by Jonsson et al (US004957745) for the same rationale recited in prior Office Action dated 10/31/2007.

(6). **Claims 27-30** and **32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinecke et al (US04056497) in view of Greenwald et al (US03944513), further in view of Contrada et al (US06646046B2) and Zellstoffwerke (GB01141165) for the same rationale recited in prior Office Action dated 10/31/2007.

(7). **Claims 7** and **8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurth et al (US03875099) in view of Bohme et al (US03890292), evidenced by Palowowski et al (US05626655A), Pons et al (US04101490) and "Polymer Technology Dictionary" by Tony Whelan.

As to an aqueous film coating composition dispersion prepared by polymerizing a mixture of monomers in the presence of water to form a substantially uncrosslinked copolymer, the mixture of monomers consists of an acrylic acid or an ester thereof in the range 40 to 80 wt%; a methacrylic acid or an ester thereof in the range 20 to 60 wt%; a polymerizable surfactant in the range 0.01 to 9 wt% in **independent claim 7** and formula I in **independent claim 8**, Kurth et al (US03875099) disclose free radical emulsion polymerization involving novel incremental addition of acrylic monomers to prepare high viscosity, freeze-thaw stable dispersions (Title).Emulsion polymerization is preferably carried out using a small amount of water together with emulsifying agent and polymerization initiator. The monomer mixture is emulsified in a large amount of water (Col. 5, line 14-28). More specifically, the resin dispersions of polymers is formed from a). 87.5 to 99.5 percent of at least one alkyl ester of acrylic acid or of methacrylic acid; b). 2.5 to 0.5 percent of at least one α, β-ethylenically unsaturated mono- or di-carboxylic

acid and c). 0 to 10 percent of at least one other vinyl or vinylidene monomer copolymerized with, each of percentage is by weight of the total mixture of monomers to be polymerized (Col. 3, line 10-21). As α, β-ethylenically unsaturated polymerizable mono- or di-carboxylic acid, acrylic acid, methacrylic acid and itaconic acid are preferred (Col. 3, line 39-41) – which reads on the 1st two monomers and their wt% as claimed. The nature of the non-ionic emulsifier which may be present during the polymerization (instead of an anionic material) is not critical, and the materials conventionally used in emulsion polymerization are suitable. These include, for example, polyalkylene oxide esters of fatty acids such as palmitic or stearic acid, alkyl aryl polyether alcohols, and the like (Col. 6, line 20-26) as shown in the example 2, the emulsifier is calculated being about 0.23 wt% of the monomer mixture (Col. 8, line 46-55). By the inclusion of few percent of N-methylol acrylamide or of ethers of these methylol compounds, dispersions are obtained which can be used to produce films which are crosslink-able on heating (Col. 3, line 54-58) – therefore, it is not cross-linked dispersion after the polymerization.

Kurth et al (US03875099) **do not teach** the specific non-ionic surfactant as claimed in formula (I).

However, Bohme et al (US03890292) **teach** non-ionic monomer for adhesive compositions and tapes (Title). Non-ionic monomer such as water soluble polyoxyalkylene ester of α, β unsaturated monocarboxylic acid (Abstract, line 7-9) such as Tergitol 15-S-12 by Union Carbide (Col. 2, line 89) – used in aqueous polymerization.

As evidenced that water soluble polyoxyalkylene ester of α, β unsaturated monocarboxylic acid is a non-ionic surfactant – Tergitol series surfactants by Pawlowski et al (US05626655A) and teaching cited that non-ionic surface active agents are typified by polyoxyethylene condensation products in which the active groups are oxyethylene groups (the hydrophobic part) on page 272 in "Polymer Technology Dictionary". Further evidenced that it has been proposed to use emulsifiers containing ethylenically unsaturated groups, so that they can be incorporated into the polymer in an aqueous phase by Pons et al (US04101490) (Col. 1, line 7-26).

Therefore, it would have been obvious at time of the invention to use monomer of disclosed by Bohme et al for the non-ionic surfactant of Kurth et al because the monomer of Bohme et al is species, the non-ionic surfactant of Kurth et al is genus, one of ordinary skills in

the art would recognize that all species work well for genus, motivated by a reasonable expectation of success. *In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).*

As to an aqueous film coating dispersion for pharmaceutical formulations in **independent claims 7-8**, because the composition of aqueous polymer dispersion disclosed by Kurth et al (US03875099) is substantially identical to the aqueous film coating dispersion of applicants, it will be useful in film coating for pharmaceutical formulations as well. The intended use is not considered as limitation and of no significance in the claim construction.

Response to Arguments

(8). Applicants' arguments filed 04/30/2008 have been fully considered but they are not persuasive.

The 1st argument raised by Applicants is the teaching of prior art Reinecke et al (US04056497) failing to disclose or suggest aqueous film coating dispersion for pharmaceutical formulations, wherein the aqueous film coating dispersion is prepared from the polymerization of a monomer mixture to form a substantially uncross-linked copolymer. In reviewing the teaching of Reinecke et al (US04056497), it recites: An aqueous dispersion of a cross-linkable acrylic ester copolymer – Col. 7, line 60 - 61). The copolymers can be cross-linked with alkalies after the polymerization (Abstract, line 5-6). The pharmaceutical application recited by instant claim is intended use, as long as the composition of mixture meets the limitations of instant claim, it would be useful for the pharmaceutical applications as well.

The 2nd argument raised by Applicants is the teaching of prior art Greenwald et al (US03944513) being far removed from pharmaceutical applications. The teaching of removal of emulsifier relies on disclosure of Greenwald et al (US03944513) for the combined arts for rejection. Moreover, even Greenwald et al (US03944513) do not disclose the removal of emulsifier is for pharmaceutical application, the desires of removing impurities such as emulsifier for the better quality of the product is well known in the art as cited by Greenwald et al (US03944513) on Col. 1, line 9-21. Therefore, the combining is proper.

Applicant's arguments with respect to claims 9-14 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IVES WU whose telephone number is (571)272-4245. The examiner can normally be reached on 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Duane Smith can be reached on 571-272-1166. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Examiner: Ives Wu
Art Unit: 1797
Date: August 7, 2008

/Duane S. Smith/
Supervisory Patent Examiner, Art Unit 1797